

EXHIBIT 24

**U.S. F.D.A., Truthful Prescription Drug Advertising
and Promotion**

Truthful Prescription Drug Advertising and Promotion

FDA's Bad Ad program is an outreach program designed to educate healthcare providers about the role they can play in helping the agency make sure that prescription drug advertising and promotion is truthful and not misleading.

[Case Studies \(/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm258719.htm\)](#)

The Bad Ad Program is administered by the agency's Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research. The program's goal is to help raise awareness among healthcare providers about misleading prescription drug promotion and provide them with an easy way to report this activity to the agency e-mail BadAd@fda.gov or call 855-RX-BADAD.

[Bad Ad Course \(<http://www.accessdata.fda.gov>\)](#)

Bad Ad Course and Educational Case Studies:

- As part of FDA's Bad Ad program, OPDP has an e-learning course and case studies to raise healthcare providers (HCP) and HCP students' awareness of misleading prescription drug promotion and other common regulatory concerns. Please click on the buttons to the right to access these resources.

Content on this Page

- [Bad Ad Program: 2011-2012 Year End Report \(<http://wayback.archive-it.org/7993/20161022170956/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm258719.htm>\)](#) (FDA Archive)
 - [Bad Ad Program: 2010-2011 Year End Report \(<http://wayback.archive-it.org/7993/20161022170953/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/UCM320688.pdf>\)](#) (FDA Archive)
 - [Examples of Violations](#)
 - [Frequently Asked Questions](#)
 - [Report: Contact Information](#)
 - [The OPDP Mission](#)
- ["What To Do About Misleading Drug Ads" Video \(<http://www.medscape.com/viewarticle/754890>\)](#) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/Web-sitePolicies/Disclaimers/default.htm>) (Medscape Today)

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Prescription drug advertising must:

- Be accurate
- Balance the risk and benefit information
- Be consistent with the prescribing information approved by FDA
- Only include information that is supported by strong evidence

What types of promotion does OPDP regulate?

- TV and radio advertisements
- All written or printed prescription drug promotional materials
- Speaker program presentations
- Sales representative presentations

OPDP does not regulate promotion of:

- Over-the-Counter Drugs
- Dietary Supplements
- Medical Devices

Common Violations:

- Omitting or downplaying of risk
- Overstating the effectiveness
- Misleading drug comparisons

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Examples of Violations

Example of Omission of Risk

You attend a speaker program which features a slide show that presents efficacy information about Drug X, but no risk information.

This presentation would be misleading because it fails to include a fair balance of benefit and risk information for Drug X.

Example of Overstating the Effectiveness

"Doctor Smith, Drug X delivers rapid results in as little as 3 days."

This presentation is misleading because the majority of patients studied in the clinical trials for Drug X showed results at 12 weeks, with only very few showing results in 3 days.

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Frequently Asked Questions

1. Can I report anonymously?

Yes, anonymous complaints often alert FDA to potential problems. However, complaints accompanied by names and contact information are helpful in cases for which FDA needs to follow-up for more information.

2. Will OPDP be able to stop the misleading promotion?

In many cases, yes, especially if the appropriate evidence is provided. Evidence can include the actual promotional materials or documentation of oral statements made by company representatives.

3. What will happen to my complaint once I have contacted OPDP?

The information you provide will be sent to the Regulatory Review Officer in OPDP responsible for this class of drugs. The reviewer will evaluate it and determine if it may serve as the basis for a potential enforcement action or as valuable information for our ongoing surveillance activities.

4. How do I learn more?

To learn more about OPDP in-service training for large medical group/hospitals call 301-796-1200.

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Report: Contact Information

The Office of Prescription Drug Promotion (OPDP) (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm)

Phone: 855-RX-BADAD or 855-792-2323

E-Mail: BadAd@fda.gov (<mailto:BadAd@fda.hhs.gov>)

Write:

FDA/CDER/OPDP
5901-B Ammendale Rd
Beltsville, MD 20705-1266

Fax: 301-847-8444 or 301-847-8445

OPDP's Mission

OPDP is responsible for ensuring truthful advertising and promotion of prescription drugs.

Our mission is to...

- Protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated.
- Guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs.

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Related Information

- **Key Points of the Bad Ad Program (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm211498.htm)**